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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/796,328	03/08/2004	Roberta Lee	RUBI5531D1C3	2106

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EXAMINER	
TRUONG, KEVIN THAO	

ART UNIT	PAPER NUMBER
3734	

DATE MAILED: 05/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/796,328	LEE ET AL.	
	Examiner	Art Unit	
	Kevin T. Truong	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *Election to restriction 05/05/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *50-58* is/are pending in the application.

4a) Of the above claim(s) *55-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/05;10/04;3/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 50-54, drawn to a method of removing a tissue specimen from a patient, classified in class 600, subclass 564.

   II. Claims 55-58, drawn to a device for collecting a tissue specimen from a patient, classified in class 606, subclass 159.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the device as claimed can be used in a materially different process. For example: it can be used for dissecting tissue along the blood vessel and limited to the method of removing a tissue specimen from a patient.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

5. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Alan Young on 05/05/2006 a provisional election was made without traverse to prosecute the invention of Group I, claims 50-54. Affirmation of this election must be made by applicant in replying to this Office action. Claims 55-58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to

be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 50-54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,440,147. Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively broad subject matter claimed in the instant application such as the method of removing tissue including a shaft with tissue collection element coupled to the distal end of the shaft for collecting tissue thereof, which would have been obvious in view of the relatively detailed subject matter of the patent claims.

10. Claims 50-54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No: 6,689,145. Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively broad subject matter claimed in the instant application such as the method of removing tissue including a shaft with tissue collection element coupled to the distal end of the shaft for collecting tissue thereof, which would have been obvious in view of the relatively detailed subject matter of the patent claims.

11. Claims 50-54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,702,831. Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively broad subject matter claimed in the instant application such as the method of removing tissue including a shaft with tissue collection element

coupled to the distal end of the shaft for collecting tissue thereof, which would have been obvious in view of the relatively detailed subject matter of the patent claims.

12. Claims 50-54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,849,080. Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively broad subject matter claimed in the instant application such as the method of removing tissue including a shaft with tissue collection element coupled to the distal end of the shaft for collecting tissue thereof, which would have been obvious in view of the relatively detailed subject matter of the patent claims.

13. Claims 50-54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,863,676. Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively broad subject matter claimed in the instant application such as the method of removing tissue including a shaft with tissue collection element coupled to the distal end of the shaft for collecting tissue thereof, which would have been obvious in view of the relatively detailed subject matter of the patent claims.

14. Claims 50-54 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,764,495. Although the conflicting claims are not identical, they are not patentably distinct from each other because the relatively broad subject matter claimed in the instant application such as the method of removing tissue including a shaft with tissue collection element

coupled to the distal end of the shaft for collecting tissue thereof, which would have been obvious in view of the relatively detailed subject matter of the patent claims.

Claim Rejections - 35 USC § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

16. Claims 50-54 are rejected under 35 U.S.C. 102(e) as being anticipated by Burbank et al. (U.S. 6,331,166).

Note in figures 8-10 of Burbank et al, teaches the method of removing tissue from a patient including the steps of providing a shaft (30) having a tissue collection element (col. 5, lines 16-21 and col. 8, lines 39-46) and a cutting element (20) disposed on the distal end of said shaft (30), wherein the tissue collection is configured to isolate the collected tissue specimen (54) from the patient.

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claims 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Heaven et al. (U.S. 5,611,803).

Note in figures 3 and 4A-4F, of Heaven et al, teaches the method of removing tissue from a patient including the steps of providing a shaft (38) having a tissue

collection element (30) and a cutting element (32) disposed on the distal end of said shaft (38), wherein the tissue collection (30) is configured to isolate the collected tissue specimen (42) from the patient.

18. Claims 50-54 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk et al. (U.S. 5,417,697).

Note in figures 5A-5C of Wilk et al, teaches the method of removing tissue from a patient including the steps of providing a shaft (56) having a tissue collection element (70) and a cutting element (74) disposed on the distal end of said shaft (56), wherein the tissue collection (70) is configured to isolate the collected tissue specimen (PO) from the patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin T. Truong whose telephone number is 571-272-4705. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kevin T. Truong
Primary Examiner
Art Unit 3734

ktt